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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

KIM, YOUNG J

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 04/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/996,024

Applicant(s)

SVENDSEN, ALLAN

Examiner

Young J. Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 15 and 20-22 is/are pending in the application.
- 4a) Of the above claim(s) 4-10, 15 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 20 and 21 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.


Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Sequence Comply Notice* 

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-9, 20, and 21, drawn to a method for producing a variant of a parent pullulanase via nucleic modification, classified in class 702, subclass 27.
- II. Claims 10, 15, and 22, drawn to a method for producing a variant of a parent pullulanase via protein modeling, classified in class 702, subclass 27.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method of II does not require the pullulanase of I. In addition, the method of I is drawn to producing a pullulanase variant by altering a nucleic acid sequence while the method of II is drawn to the modification of protein sequences.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Species Requirement for Group I

This application contains claims directed to the following patentably distinct species of the claimed invention: Claims are drawn to pullulanases of various altered activities.

- a) increased isoamylase activity (claim 3)

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b) improved thermostability, determined by:

- i) differential scanning calorimetry (DSC) (claim 4)
- ii) $T_{1/2}$ assay for liquefaction (claim 5)
- iii) assay for residual activity after liquefaction (claim 6)
- iv) $T_{1/2}$ assay for saccharification (claims 7-9)

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 2, 20, and 21 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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During a telephone conversation with Mr. Jason Garbell on February 12, 2002 a provisional election was made with traverse to prosecute the invention of I and species of (a) drawn to altered isoamylase activity, effectively, claims 1-3, 20, and 21. Affirmation of this election must be made by applicant in replying to this Office action. Claims 4-10, 15, and 22 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Specification - Sequence Rules

This application contains sequence disclosures that are encompassed by the definition for nucleotide and/or amino acid sequences set for in 37 CFR 1.82(a)(1) and (a)(2). On page 63, various primer sequences (which are more than 10 contiguous nucleotides in length) are disclosed without their SEQ ID Numbers. In addition, this application seems to be missing a paper copy of the Sequence Listing for the SEQ ID Numbers already present in the application. Therefore, this application fails to comply with the requirement of 37 CFR 1.821 through 1.825 (see also the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotides Sequences And/Or Amino Acid Sequence Disclosures).

Applicants are required to fully comply for the response to be complete.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 09/514,599, filed on February 28, 2000.

Claim Rejections - 35 USC § 112

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 20, and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and its dependent claims 2, 3, 20, and 21 are indefinite because sub-step (b) requires an alteration of a structure (in amino acid) in a parent pullulanase while the modification of nucleic acid in sub-step (c) does not appear to be drawn to this alteration. Therefore, it is unclear whether the "modification" of the nucleic acids in sub-step (c) reflects the alteration determined in the sub-step (b), thereby producing a variant pullulanase of this alteration or another variant pullulanase is produced.

Claim 1 and its dependent claims 2, 3, 20, and 21 are indefinite for the recitation of the sub-step (a), wherein the step recites, "modeling the parent pullulanase on the three-dimensional structure of SEQ ID NO: 1 to produce a three-dimensional structure of the parent pullulanase," because it is unclear what this step is intended to achieve. In other words, it is unclear in what way SEQ ID NO: 1 is involved in modeling of the parent pullulanase. Further, SEQ ID Number 1 is a nucleic acid sequence. Therefore, it is unclear whether the phrase, "three-dimensional structure of SEQ ID NO: 1" is intended to mean the fold structure of the nucleic acid sequence or the three-dimensional structure of its encoded protein.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 20, and 21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure would require undue experimentation are summarized in *In Re Wands* (858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988)). They include (A) the quantity of experimentation necessary, (B) the amount of direction or guidance presented, (C) the presence or absence of working examples, (D) the nature of the invention, (E) the state of the prior art, (F) the relative skill of those in the art, (G) the predictability or unpredictability of the art, and (H) the breadth of the claims.

A) Quantity of experimentation necessary: The invention requires a step of modeling a parent pullulanase on the three-dimensional structure of SEQ ID NO: 1, which is a DNA sequence. After the three-dimensional structure of the parent is identified, various alterations are introduced to the parent pullulanase to produce a variant pullulanase with an altered property. Therefore, the quantity of experimentation would be largely dependent on the production of a protein sequence and its three-dimensional structure of SEQ ID Number 1 and empirical verification of the altered property of the resulting variant pullulanases.

B) Amount of direction or guidance presented: The specification and prior provides for alteration of proteins (via deletions, substitutions, or insertions) for the purpose of finding an enhanced or altered property.

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C) Absence of working example: There are no working examples in the specification for variant pullulanases of altered properties.

D) Nature of the invention: The nature of the invention is drawn to producing a variant protein of altered property based on a polynucleotide sequence.

E) State of prior art: Patent 6,265,197 B1 discloses a variant pullulanase of altered properties such as thermostability, increased residual enzyme activity (claims 1-8).

F) Skill level: The skill level of the artisan is high.

G) The unpredictability in the art: The feasibility of producing a pullulanase of altered property via alteration in its sequence is predictable as demonstrated by the above prior art.

H) Breadth of claims: The breadth of claims encompasses a method of modeling a parent pullulanase based on a three-dimensional structure of a nucleic acid sequence.

Although the prior art as well as the specification provides for a method of modeling a parent pullulanase based on a three-dimensional structure of the protein (*i.e.*, amino acid sequence), it would require an undue amount of experimentation to practice the claimed method which requires a skilled artisan to model a three-dimensional structure of a parent pullulanase based on a nucleic acid sequence of a template protein because neither the prior art nor the specification provides any guidance for such a method.

Conclusion

No claims are allowed.

Inquiries

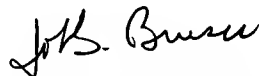
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (703) 308-9348. The Examiner can normally be reached from 8:30 a.m. to 7:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the

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Examiner's supervisor, Gary Benzion, can be reached at (703) 308-1119. Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. The Fax number is (703) 746-3172. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Young J. Kim

4/6/03



JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER